



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1067]

Draft Guidance for Industry on Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products--Content and Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products--Content and Format." The recommendations in the draft guidance are intended to help ensure that the labeling is clear, useful, informative, and to the extent possible, consistent in content and format.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville,

MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonas Santiago, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6358, Silver Spring, MD 20993-0002, 301-796-5346; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products--Content and Format." This draft guidance provides recommendations for the "Patient Counseling Information" section on the following: How to decide what topics to include in the section, how to present information within the section, and how to format and organize section contents.

This guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the content and format of the labeling for human prescription drug and biological products. In the Federal Register of January 24, 2006 (71 FR 3922), FDA published a final rule on labeling for human prescription drug and biological products. The final rule and

additional guidances can be accessed at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm>. The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on the content and format of the "Patient Counseling Information" section of labeling for human prescription drug and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. The Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

#### IV. Electronic Access

Persons with access to the Internet may obtain the document at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>.

Dated: September 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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